REMARKS

I. Introduction

Receipt is acknowledged of a non-final office action dated March 9, 2004. In the action, claims 1-7, 9, 11, 16, 17, 59, 105, 151 and 184-192 were rejected as allegedly lacking utility and enablement, claims 1, 3, 6, 7, 9, 11, 16, 17 and 184-192 as allegedly failing to meet the written description requirement, and claims 1-7, 9, 11 and 184-192 as allegedly indefinite. In addition, the disclosure was objected to for containing an embedded hyperlink.

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

II. Status of the Claims

Claims 1, 11, 186 and 190 have been amended to more clearly recite the presently claimed invention. Applicants also added new claims 193-195. Support for the revised claims can be found on page 27, lines 7-9 (claims 1 and 11), and on page 21, lines 26-34 (claims 186 and 190). Support for the new claims can be found on page 27, lines 4-5, and page 16, line 32, to page 17, line 29. Upon entry of this amendment, claims 1-7, 9, 11, 16, 17, 59, 105, 151, and 184-195 will be under examination.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested.

III. Objections to the Specification

The specification was objected to for containing an embedded hyperlink. Applicants have amended the specification to delete the link.

IV. Rejection of the Claims Under 35 U.S.C. § 101

Claims 1-7, 9, 11, 16, 17, 59, 105, 151 and 184-192 were rejected under 35 U.S.C. § 101 as allegedly lacking utility. Specifically, the examiner stated that "[n]o specific activity is

exemplified or attributed to any of the 54 CCYPRs, and no direction on how...any of the polynucletoides can be used in such a manner is provided." Office Action at 3.

In addition, the claims were rejected because "the specification does not provide a basis for stating that the polypeptide [of SEQ ID NO: 36] and encoding polynucleotides have homology [to the malignant brain tumor protein taught in Koga] and therefore[,] implied potential like activity." Office Action at 4. Further, the examiner contended, "[a]pplicants are not in possession of either full-length product, and the specification provides information that is incongruent and/or lacking when the products are compared to the art of record." Office Action at 5.

Applicants respectfully traverse this ground for rejection.

A. The claimed CCYPRs of the present invention regulate the cell cycle and cell proliferation

The specification describes the CCYPRs of the present invention as human cell cycle and cell proliferation proteins. The claimed CCYPRs have "chemical and structural similarity" to cell cycle and proliferation proteins "in the context of sequences and motifs." Specification at 40.

In addition, one of skill in the art would know, based on the teachings in the specification, that the claimed CCYPRs are suitable for use in the diagnosis and treatment of cell signaling and proliferative disorders, and what specific diseases and disorders fall under these categories. In fact, the specification teaches that "the expression of CCYPR is closely associated with inflammation, trauma, cell proliferation and cancer" and further discloses which disorders are associated with decreased expression of CCYPR. Specification at 40-41.

Furthermore, the specification discloses how treatment with polynucleotides encoding the claimed CCYPRs can be effected. For example, the present application describes the administration of a vector capable of expressing CCYPR (to treat a disorder associated with decreased activity of CCYPR) as well as a CCYPR antagonist (to treat a disorder associated with increased activity of CCYPR), agonist, antibody, or complementary sequences, and methods for making such compositions. Specification at 42-50.

B. The specification supports utility for the claimed CCYPR polypeptides and the contention that the claimed polypeptides having SEQ ID NO: 36 share homology with a protein that affects tumor cell proliferation

The present specification discloses in Table 2 features of the claimed CCYPR polypeptides, including potential motifs and sequences homologous to those described in the art. Even assuming that the claimed polypeptides having SEQ ID NO: 36 "is over 220 amino acids shorter than the h-I(3)mbt [brain tumor protein] taught in Koga" (Office Action at 4), this does not mean that the claimed polypeptides do not have activity similar to the Koga protein. In fact, one of skill in the art would know that polypeptide variants (including shorter variants) of a particular protein can possess the same activity as the larger protein. Moreover, applicants are only claiming polypeptides, and the polynucleotides encoding them, that have the ability to regulate the cell cycle and cell proliferation.

As Applicants' claims meet the statutory requirement for utility, withdrawal of this ground for rejection is respectfully requested.

V. Rejection of the Claims Under 35 U.S.C. § 112, first paragraph

A. Enablement Rejection

Claims 1-7, 9, 11, 16, 17, 59, 105, 151 and 184-192 were rejected under 35 U.S.C. § 112, first paragraph, because "since the claimed invention is not supported by either...the asserted utility or a well established utility for the reasons [already described,]...one skilled in the art clearly would not know how to use the claimed invention." Office Action at 5. Applicants respectfully traverse this ground for rejection.

As described above, the presently claimed CCYPR polypeptides and polynucleotides that encode them are suitable for use in treating, for example, cell proliferation disorders. Specification at 40. Specific conditions are also exemplified, as well as methods for making such therapeutic compositions. Thus, a skilled artisan, based on the teachings in the instant specification, would know how to make and use the presently claimed invention.

As Applicants' claims meet the statutory requirement for enablement, withdrawal of this ground for rejection is respectfully requested.

B. Written Description Rejection

Claims 1, 3, 6, 7, 9, 11, 16, 17 and 184-192 were rejected under 35 U.S.C. § 112, first paragraph, as allegedly failing to meet the written description requirement. Specifically, the examiner stated that "[t]he Claims refer to percent identity, biologically active fragments, and imunologically active fragments, polynucleotides that hybridize to the claimed polynucleotides, and so forth" but the instant specification "does not describe any of these variants[] or any variant having any activity." Office Action at 5-6. Applicants respectfully traverse this ground for rejection.

A skilled artisan would know, based on the teachings in the present specification, what is meant by a biologically active and immunologically active fragment of the claimed CCYPR proteins and nucleic acids encoding them. Indeed, the present application describes that a biologically active fragment of CCYPR as "having structural, regulatory, or biochemical functions of a naturally occurring molecule" and defines an immunogenic fragment as being "capable of eliciting an immune response." Specification at 16 and 22, respectively. Furthermore, the present specification discloses how to select regions of immunogenicity in the CCYPR amino acid sequences provided therein, and how to make CCYPR antibodies. Specification at 73-74, Example XIII.

In addition, the claimed polypeptide variants share at least 90% sequence identity with specific CCYPR polypeptides and the claimed variants can regulate cell proliferation. This functional feature can be assayed by methods known in the art as well as by the teachings in the present specification. For example, the specification describes how to measure CCYPR activity and how to assess function of the CCYPR sequences. Specification at 72-73, Examples XI and XII. Also, a skilled artisan would know which amino acids can be substituted without altering the structure of the polypeptide backbone in the area of substitution or the function of the polypeptide. *See* specification at 17.

Thus, polypeptide variants, nucleic acid variants, and biologic and immunogenic fragments thereof are adequately described in the instant application. Nevertheless, in the

interest of expediting prosecution, applicants amended the claims so as to be drawn to polypeptides, polynucleotides, and fragments thereof that regulate cell proliferation or are capable of inducing an immune response.

As Applicants' claims and application meet the statutory requirement for written description, withdrawal of this ground for rejection is respectfully requested.

VI. Rejection of the Claims Under 35 U.S.C. § 112, second paragraph

Claims 1-7, 9, 11 and 184-192 were rejected under 35 U.S.C. § 112, second paragraph, as allegedly indefinite. Specifically, the examiner stated that the activity of a biologically active and immunogenically active fragment as recited in claim 1 is not set forth, and conditions for hybridization are not set forth in claims 186 and 190. Applicants respectfully traverse this ground for rejection.

A skilled artisan would know what is meant by biologically active and immunogencially active. In fact, these terms are defined in the present specification on pages 16 and 22. But in the interest of expediting prosecution, and without acquiescing to the examiner's rejection, applicants amended claim 1 to recite such activity. Support for this amendment can be found on pages 16 and 22 of the instant application.

Likewise, applicants amended claims 186 and 190 to recite hybridization "under high stringency conditions." Support for this amendment can be found on page 21 of the present specification.

Therefore, for at least these reasons, rejection of the pending claims should be withdrawn.

CONCLUSION

Reconsideration of the present application in view of the foregoing amendments and arguments is kindly requested.

It is respectfully urged that the present application is now in condition for allowance. Early notice to that effect is earnestly solicited.

Examiner Carlson is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application

Respectfully submitted,

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